

REMARKS

This paper is being filed in response to the Notice of Non-Compliant Amendment mailed July 17, 2003 and is intended to replace Applicants' Response to Restriction Requirement and Preliminary Amendment mailed on May 30, 2003.

The Office Action mailed May 2, 2003 contains revised and additional restriction requirements.

Applicants would like to thank the Examiner for the courtesy extended to Applicants' attorney in a telephone conference on May 29, 2003. During the course of the discussion Applicants' attorney expressed concern about the restriction requirement between Groups G1 and G2 on the basis that G1 and G2 are not being patentably distinct inventions. It was discussed that Applicants will respond to the restriction requirement by making an election with traverse to maintain the option of arguing the propriety of the restriction requirement between Groups G1 and G2 in the event Groups G1 and G2 are not rejoined during prosecution.

During the telephone conference on May 29, 2003, the scope of Claim 1 with regard to use of the term "having" was discussed. The Examiner informed Applicants' attorney that the claim was construed by him to be open-ended by use of the term "having." Applicants have hereby amended Claim 1 to clarify the subject matter of the claim by reciting that "Xaa₁ is the N-terminal amino acid of the peptide."

A. Election Of Invention

The Examiner requires that Applicants elect one of Groups 34-41, each of which the Examiner considers a distinct invention. Each of these Groups is limited to certain specified claims and to subgenus G1 or subgenus G2. Thus, for example, Group 34 is limited to Claims 1-31 and subgenus G2, and Group 35 is limited to Claims 1-31 and subgenus G1.

Applicants hereby elect Group 34 (Claims 1-31, subgenus G2). Applicants elect Claims 1-31 without traverse. However, Applicants strongly traverse the restriction requirement to the extent that it requires an election of subgenus G1 or subgenus G2.

Subgenera G1 and G2 have been created by the Examiner. Subgenus G1 is compounds whose structures cannot be determined without consulting a document that has been incorporated

by reference. Subgenus G2 is compounds for which the structures are apparent without consulting a document that has been incorporated by reference.

There is no basis in the statute, regulations or even the Manual of Patent Examining Procedure (MPEP) for restriction of Applicants' claims to one of these two subgenera. Grouping compounds by whether or not they are based on material which is incorporated by reference into the application does not define groups of compounds which are independent and distinct inventions or which share common structural or functional characteristics. It is a wholly arbitrary and improper division.

The fact that this division is improper is illustrated by the following. By taking the position that Group 34 (Claims 1-31, subgenus G2) and Group 35 (Claims 1-31, subgenus G1) define distinct inventions, the Examiner is taking the position that these groups are patentable over each other and will support separate patents. MPEP §§ 802.01, 803. Thus, following the Examiner's logic to its ultimate conclusion, two patents could potentially issue with identical claims. However, the claims in one patent would have a different meaning than the meaning of the identical claims in the other patent. Such a result is clearly not permissible.

The Examiner has given examples of the differences between subgenera G1 and G2. However, to Applicants, the dividing line between the two subgenera is still quite unclear and will never be clear. Applicants submit that the reason for the lack of clarity is that the division is not based on a clear-cut structural or functional difference, as it should be.

The Examiner's primary reason for creating subgenera G1 and G2 seems to be a concern with hypothetical claims that Applicants might assert during prosecution, not with the current claims. As noted in Applicants' previous response, additional restriction requirements to claims added or amended during prosecution can be made at the time they are added or amended. 37 C.F.R. § 1.145. Further, any restriction requirement at this time must concern only the current claims. MPEP § 806.01. Also see 35 U.S.C. § 121 ("If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions." [Emphasis added.]).

The Examiner also raises the issue of the Examiner's examining burden. However, examining burden alone cannot be the reason for a restriction requirement. MPEP §§ 803. Also see

35 U.S.C. § 121 and 37 C.F.R. §§ 1.142-1.146. Further, as a practical matter, as a result of Applicants elections of Claim 1-31 and several additional species, the Examiner's examination burden should be substantially lessened.

For all of the foregoing reasons, Applicants request that the portion of the restriction requirement requiring election of subgenus G1 or G2 be withdrawn and that Claims 1-31 be examined in their entirety (subject, of course, to examination first of the elected species).

B. Species Elections

First, the Examiner requires that Applicants further restrict their elected tetrapeptide (Asp Ala His Lys) to specify which amino acids are D-amino acids and which are L-amino acids. Applicants hereby elect the tetrapeptide Asp Ala His Lys in which all of the amino acids are L-amino acids. Claims 1-11 and 21-31 read on the elected species.

On pages 6-11 of the Office Action, the Examiner requires election of several additional species. Applicants elect the following species for Group 34 (listed in the same order as the bullet points on page 7):

- heart tissue damage,
- (b) will undergo radiation therapy,
- (b) will undergo open-heart surgery,
- (b) will undergo organ transplant,
- (a) exhibiting symptoms of ischemia,
- (a) administered to meet one of the criteria of Claim 24, and
- ischemia.

Respectfully submitted,

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July 31, 2003